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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/039,752 | 01/02/2002 | Zhihua Qiu | UNI.20 | 1617 |

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| EXAMINER | |
|---|---|
| PRATS, FRANCISCO CHANDLER | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1651 | 6 |

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/039,752 | QIU ET AL. | |
| | Examiner | Art Unit | |
| | Francisco C Prats | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Claims 1-21 are presented for examination.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qui et al (U.S. Pat. 6,346,679) or Qiu et al (U.S. Pat. 6,133,440) in view of Hansen et al (U.S. Pat. 5,254,174) or DeFrees (U.S. Pat. 6,454,946).

Each of '679 and '440 disclose the precise process recited in applicant's claims, with the exception of the nanofiltration

step recited as step (e). However, each of Hansen and DeFrees discloses that at the time of applicant's invention it was known to be advantageous to treat polysaccharide-containing compositions of the type disclosed in the '679 and '440 patents by nanofiltration, so as to remove impurities therefrom. See Hansen at column 8, lines 23-25. ("Nanofiltration also results in the removal of low molecular weight proteins and amino acids, so that the purity of the inulide mixture is improved.") See also DeFrees, at abstract. ("The carbohydrates are purified away from undesired contaminants such as compounds present in reaction mixtures following enzymatic synthesis or degradation of oligosaccharides.")

(As an aside, note that Hansen and Defrees are applied in the alternative, not to supplement any shortcoming in either reference. Similarly the '679 and '440 patents are applied alternatively. )

The artisan of ordinary skill, recognizing from Hansen or DeFrees the advantages of using nanofiltration to improve the purity of the pharmaceutical product made according to the methods disclosed in the '679 and '440 patents, clearly would have been motivated to have added a nanofiltration step to the processes in the '679 and '440 patents. That is, based on the disclosures of either Hansen or DeFrees, the artisan of ordinary

skill would have reasonably expected to have improved the properties of the product made by the process of the '679 and '440 patent, and therefore would have been motivated by Hansen/DeFrees to have added a nanofiltration step to the process disclosed in the '679 and '440 patents. A holding of obviousness is therefore required.

It is noted that applicant claims priority to the applications which matured into the '440 and '679 patents. However, the effective filing date of the subject matter in claims 1-21 of the instant application is January 2, 2002, which is more than 1 year after the October 17, 2000, issue date of the '440 patent. The '440 patent is therefore clearly applicable as prior art to claims 1-21, despite the priority claim to the application which matured into the '440 patent. The '679 patent is applicable to the present claims under 35 U.S.C. 102(e), because the '679 patent is a patent "to another" under that statute, since the instant case has a different inventive entity than the '679 patent.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple

assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,436,679 in view of of Hansen et al (U.S. Pat. 5,254,174) or DeFrees (U.S. Pat. 6,454,946).

As discussed above, the '679 patent claims the precise process recited in applicant's claims, with the exception of the nanofiltration step recited as step (e). However, as also discussed above, each of Hansen and DeFrees discloses that it was known to be advantageous at the time of applicant's invention to treat polysaccharide-containing compositions of the type made by the process in the '679 patent by nanofiltration, so as to remove impurities therefrom. Thus, the artisan of ordinary skill, recognizing from Hansen or DeFrees the advantages of using nanofiltration to improve the purity of the pharmaceutical product made according to the methods recited in

the '679 patent, clearly would have been motivated to have added a nanofiltration step to the processes recited in the claims of the '679 patent. That is, based on the disclosures of either Hansen or DeFrees, the artisan of ordinary skill would have reasonably expected to have improved the properties of the product made by the process recited in the claims of the '679 patent, and therefore would have been motivated by Hansen/DeFrees to have added a nanofiltration step to the process recited in the claims of the '679 patent. A terminal disclaimer over the '679 patent is therefore clearly required.

As discussed above, claims 1-21 directed to an invention not patentably distinct from claims 1-10 of commonly assigned U.S. Pat. 6,436,679. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Pat. 6,436,679, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and

37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
May 2, 2003